Portable Oxygen Concentrator
User Manual

DELPHI

Manufactured by:

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For Help

If you have questions about the information in these instructions or about the safe operation of this device, contact Customer Service at the number listed above.

Classification

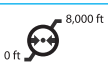
This equipment is listed with a nationally recognized testing laboratory and classified with respect to electric shock, fire, and mechanical hazards in accordance with the following standards:

- EN 60601-1 (1990), Medical Electrical Equipment, Part 1: General Requirements for Safety +A1(1993) +A2(1995) +A13(1996)
- UL 60601-1 (1st edition, 2006-04-26), Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1 (2nd edition), Medical Electrical Equipment, Part 1: General Requirements for Safety, with A1 and A2
- CAN/CSA C22.2 No. 601.1-M90 (R2005), Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-4 (2000-2004), Edition 1.1 Consolidated Edition, Medical Electrical Equipment, Parts 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems

This equipment is classified as:

- Class I
- Type BF
- IPX2
- Continuous operation at temperatures of 95°F (35°C) down to 41°F (5°C), and short-time operation for 25 minutes at temperatures up to 104°F (40°C) and 93% ± 2% relative humidity.

Explanation of Packaging and Labeling Symbols

	Caution, consult accompanying documents
	Input 18V DC, 6.7A
	Output = 90% ± 3% oxygen
	Serial number
	Catalog number
	U.S. federal law restricts this device to sale by or on the order of a physician
	No smoking
	Use no oil or grease
	No open flame when device is in use or do not incinerate
	Do not disassemble
	Separate collection for electrical and electronic equipment
	Type BF according to electrical safety requirements
	Operating atmospheric pressure limitation 0' to 8,000'
	Storage temperature limitation -4°F to 140°F (-20°C to 60°C)
	Humidity limitation 5% to 93% ± 2% non-condensing

	Do not use if packaging is damaged
	Handle with care
	Date of manufacture
	Manufacturer name and address
	Keep dry (This symbol refers to the IPX2 classification of the device)
	Dispose of used battery properly
	Do not remove filter while unit is operating
	Medical equipment with respect to electric shock, fire, and mechanical hazards in accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1
	WARNING! Do not use this device without the carrying case. Use of this device outside its carrying case may result in an electric shock hazard.
	Caution Hot Surface

Introduction

MANUAL VERSION

Please refer to this manual for detailed instructions on warnings, precautions, specifications, and additional information. Printed in U.S.A.

Electronic copies of the current version of the *Portable Oxygen Concentrator User Manual* can be found at www.delphimedical.com.

GENERAL INFORMATION

This user manual provides information for users of the Portable Oxygen Concentrator. For the sake of brevity, the terms "concentrator," "unit," or "device" are sometimes used in this document to refer to the Portable Oxygen Concentrator.

IMPORTANT:

Users should read this entire manual before operating the Portable Oxygen Concentrator. Failure to do so could result in personal injury and/or death. If you have questions about the information in this user manual or about the safe operation of this system, contact Customer Service.

TYPOGRAPHICAL CONVENTIONS

These instructions contain warnings, precautions, and notes to help call attention to the most important safety and operational aspects of the system. To help identify these items when they occur in the text, they are shown using the following typographical conventions:

WARNING:

STATEMENTS THAT DESCRIBE SERIOUS ADVERSE REACTIONS AND POTENTIAL SAFETY HAZARDS.

PRECAUTION:

STATEMENTS THAT CALL ATTENTION TO INFORMATION REGARDING ANY SPECIAL CARE TO BE EXERCISED BY THE PRACTITIONER AND/OR PATIENT FOR THE SAFE AND EFFECTIVE USE OF THE DEVICE.

IMPORTANT:

Statements calling attention to additional significant information about the device or a procedure.

Note: Statements that provide supplemental information.

INDICATIONS FOR USE

The Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.

INTENDED USE

The Portable Oxygen Concentrator is intended to deliver concentrated oxygen for adult patients with chronic pulmonary diseases such as chronic bronchitis, emphysema, asthma, or lung cancer, those in the terminal stage of cancer, or any patient requiring supplemental oxygen. The device is portable, enabling patients who need an oxygen device to be treated at home according to a clinician's prescription or direction. The Portable Oxygen Concentrator is a prescription-only device, is not intended for use in life-supporting or life-sustaining situations, and is provided non-sterile. It is designed to be used indoors or outdoors.

CONTRAINDICATIONS

The Portable Oxygen Concentrator is not intended to be used:

- in life-supporting or life-sustaining situations
- in an operating or surgical environment
- with a non-adult population
- in conjunction with flammable anesthetic or flammable materials

Warnings and Precautions

WARNINGS OVERVIEW

WARNING:

1. **CRITICAL! EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS!**
2. **DO NOT USE A PORTABLE OXYGEN CONCENTRATOR OR ANY ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE.**
3. **DO NOT ALLOW SMOKING OR OPEN FLAMES NEAR THIS DEVICE. DO NOT USE THIS DEVICE IN THE PRESENCE OF POLLUTANTS OR FUMES.**
4. **DO NOT SUBMERGE THIS DEVICE IN LIQUID. DO NOT EXPOSE TO WATER OR PRECIPITATION. DO NOT EXPOSE TO DUSTY CONDITIONS.**
5. **DO NOT USE LUBRICANTS ON THIS DEVICE OR ANY OF ITS ACCESSORIES.**
6. **ALWAYS ENSURE BATTERY IS INSERTED BEFORE USING THIS DEVICE.**
7. **IF FEELING ILL OR EXPERIENCING DISCOMFORT WHILE USING THIS DEVICE, CONTACT CLINICIAN IMMEDIATELY.**
8. **DO NOT DISASSEMBLE THIS DEVICE OR ANY OF ITS ACCESSORIES. DO NOT ATTEMPT ANY MAINTENANCE OTHER THAN TASKS DESCRIBED IN "TROUBLESHOOTING" (PAGE 20). DISASSEMBLY CAN CREATE AN ELECTRIC SHOCK HAZARD AND WILL VOID THE WARRANTY. CONTACT CUSTOMER SERVICE FOR SERVICING BY AUTHORIZED PERSONNEL.**
9. **RISK OF ELECTRIC SHOCK. DO NOT OPERATE THIS DEVICE WITHOUT THE CARRYING CASE.**
10. **THIS DEVICE IS FOR CONTINUOUS OPERATION AT TEMPERATURES OF 95°F (35°C) DOWN TO 41°F (5°C), AND SHORT-TIME OPERATION FOR 25 MINUTES AT TEMPERATURES UP TO 104°F (40°C) AND 93% ± 2% RELATIVE HUMIDITY.**

PRECAUTIONS OVERVIEW

PRECAUTION:

1. U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
2. IT IS RECOMMENDED AN ALTERNATE SOURCE OF OXYGEN BE AVAILABLE IN CASE OF POWER OUTAGE OR MECHANICAL FAILURE. CONSULT PROVIDER OR CLINICIAN FOR AN APPROPRIATE BACKUP SYSTEM.
3. NON-PRESCRIBED OXYGEN THERAPY CAN BE HAZARDOUS UNDER CERTAIN CIRCUMSTANCES. USE THIS DEVICE ONLY WHEN PRESCRIBED BY A CLINICIAN.

PRECAUTION:

4. IF YOU ARE UNABLE TO HEAR OR SEE ALARMS, DO NOT HAVE NORMAL TACTILE SENSITIVITY, OR CANNOT COMMUNICATE DISCOMFORT, CONSULT CLINICIAN BEFORE USING THIS DEVICE.
5. THIS DEVICE IS NOT DESIGNED FOR USE WITH A HUMIDIFIER OR NEBULIZER. IF A HUMIDIFIER OR NEBULIZER IS USED WITH THIS DEVICE, PERFORMANCE MAY BE DIMINISHED AND THE DEVICE MAY BE DAMAGED.
6. PATIENTS WITH A FAST BREATHING RATE REQUIRING A HIGHER OXYGEN SETTING MAY REQUIRE MORE OXYGEN THAN THIS DEVICE CAN PRODUCE. THIS DEVICE MAY NOT BE APPROPRIATE IN THAT CASE. CONSULT CLINICIAN FOR ALTERNATIVE TREATMENT.
7. ONLY USE APPROVED ACCESSORIES WITH THIS DEVICE. REFER TO THE APPROVED ACCESSORIES GUIDE FOR A COMPLETE LIST OF ACCESSORIES AND CANNULA APPROVED FOR USE WITH THIS DEVICE. USING UNAPPROVED ACCESSORIES OR CANNULA MAY IMPAIR THE PERFORMANCE OF THIS DEVICE.
8. REPLACE THE CANNULA ON A REGULAR BASIS. CHECK WITH CUSTOMER SERVICE OR CLINICIAN TO DETERMINE HOW OFTEN THE CANNULA SHOULD BE REPLACED.
9. ELECTRICAL CORD AND/OR TUBING LYING ON THE FLOOR COULD PRESENT A TRIPPING HAZARD.
10. NEVER LEAVE THIS DEVICE IN A HOT ENVIRONMENT. NEVER LEAVE THIS DEVICE IN A LOW-TEMPERATURE ENVIRONMENT. EXTREME HIGH OR LOW TEMPERATURES CAN DAMAGE THIS DEVICE.
11. IF OXYGEN CONCENTRATION DROPS BELOW THE SPECIFIED LEVEL, AN ALARM WILL INDICATE THIS CONDITION. IF ALARM PERSISTS, STOP USING THIS DEVICE, SWITCH TO AN ALTERNATE SOURCE OF OXYGEN, AND CONTACT CUSTOMER SERVICE.
12. DO NOT USE CLEANING AGENTS OTHER THAN THOSE SPECIFIED IN THIS MANUAL. ALLOW THE CLEANING SOLUTION TO DRY FROM THE CLEANED SURFACE BEFORE USE.
13. ALWAYS DISCONNECT POWER AND TURN OFF THIS DEVICE BEFORE CLEANING. SEE “MAINTENANCE AND CLEANING” (PAGE 12).
14. DO NOT OBSTRUCT AIR INTAKE OR EXHAUST WHEN OPERATING THIS DEVICE. BLOCKAGE CAN CAUSE BUILDUP OF INTERNAL HEAT AND SHUT DOWN OR DAMAGE THIS DEVICE.
15. ALWAYS USE IN A WELL-VENTILATED LOCATION.
16. DO NOT OPERATE THIS DEVICE WITHOUT THE INPUT FILTER IN PLACE. IF FILTER IS REMOVED, PARTICLES MAY BE DRAWN INTO THE SYSTEM AND MAY DAMAGE THIS DEVICE.

PRECAUTION:

17. ALWAYS OPERATE DEVICE AT THE SETTING PRESCRIBED BY A CLINICIAN. DO NOT ALTER THE SETTING UNLESS PRESCRIBED BY A CLINICIAN.
18. THIS DEVICE IS DESIGNED FOR USE BY ONE PATIENT AT A TIME.
19. THIS DEVICE MAY NOT REACH SPECIFIED OXYGEN CONCENTRATION PURITY UNTIL IT HAS BEEN IN USE FOR UP TO 10 MINUTES.
20. ALWAYS FOLLOW THE MAINTENANCE SCHEDULE AS SPECIFIED IN "ROUTINE MAINTENANCE" (PAGE 13).
21. IF THIS DEVICE INDICATES AN ABNORMAL CONDITION, SEE "TROUBLESHOOTING" (PAGE 20).
22. REMOVE BATTERY IF THIS DEVICE IS NOT GOING TO BE USED FOR MORE THAN SEVEN DAYS. STORE BATTERY IN A COOL, DRY PLACE.
23. ALWAYS FOLLOW CANNULA MANUFACTURER'S INSTRUCTIONS FOR PROPER USE.
24. ALWAYS TURN OFF THIS DEVICE WHEN NOT IN USE.
25. DO NOT USE THIS DEVICE WHILE SLEEPING UNLESS UNDER THE SUPERVISION OF A CLINICIAN.
26. DO NOT PLACE OBJECTS ON TOP OF THIS DEVICE.
27. THIS DEVICE IS RATED IPX2. DO NOT USE IN DUSTY CONDITIONS.
28. USE CAUTION WHEN TOUCHING THIS DEVICE IN HIGH AMBIENT TEMPERATURES.
29. CHECK THAT THIS DEVICE OPERATES ON BATTERY AFTER DISCONNECTING FROM THE POWER SOURCE.
30. ONLY CHARGE BATTERY IN THIS DEVICE OR IN AN APPROVED CHARGER. (SEE APPROVED ACCESSORIES GUIDE.)

IMPORTANT:

1. If an extension cord is necessary, use a UL listed 15 amp or higher cord. Do not connect any other devices on the same extension cord.
2. Inhale through nose for the concentrator to work most effectively. Inhaling through mouth may result in less effective oxygen therapy.
3. This device utilizes an oxygen-conserving delivery method, and the setting on this device may differ from your setting on a continuous flow oxygen concentrator (if you have been prescribed one). Your clinician will provide you with specific instructions based on your specific health condition and other variables.

Contents

Before You Get Started

Always inspect the device and its accessories for any sign of damage before using.

Note: While box or packaging may exhibit some damage, e.g., tears or dents, the device may still be in a usable condition.

If the device or any accessory shows any sign of damage, contact your care provider.

Before you get started, check to make sure you have the following:

- Concentrator
- Battery
- Carrying case
- AC/DC power supply

See Approved Accessories Guide for more information.

WARNING:

DO NOT USE A PORTABLE OXYGEN CONCENTRATOR OR ANY ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE.

POWER SUPPLY

The Portable Oxygen Concentrator can always be used when directly connected to a power source. However, to enhance its portability, the Portable Oxygen Concentrator is equipped with a rechargeable lithium-ion internal battery.

WARNING:

ALWAYS ENSURE BATTERY IS INSERTED BEFORE USING THIS DEVICE.

Note: Optional power supplies are available for various global use and travel. See Approved Accessories Guide for complete list.

Charging the Battery

PRECAUTION:

ONLY CHARGE BATTERY IN THIS DEVICE OR IN AN APPROVED CHARGER. (SEE APPROVED ACCESSORIES GUIDE.)

Prior to using the Portable Oxygen Concentrator for the first time, install the battery as shown in Figure 1. The battery will latch when fully seated.

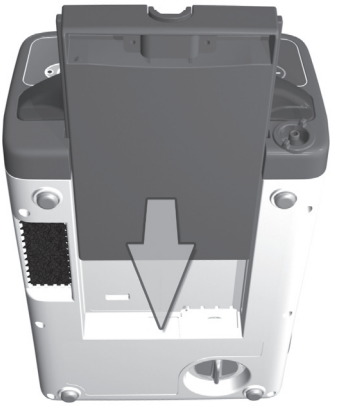


Figure 1.

Connect the AC power supply (consult Approved Accessories Guide) by plugging the round connector into the receptacle on the side of the concentrator. See Figure 2. Plug the other end of the AC power supply into a power outlet. Always use caution when inserting the power supply to a wall outlet.

Charger requirements are universal to support a wide variety of international markets, so it can be plugged into an outlet with 100-240V AC, 50-60 Hz. Allow the battery to charge for a minimum of three hours before use. Once the battery is completely charged, the device can run on battery for approximately 2-3 hours at a setting of 2.0.

Note: Battery run time may vary based on breathing rate, age of battery, and environmental conditions. See displayed text on device for battery charge status.

Figure 2.

Note: Ensure power status icon (see Figure 6, page 5) indicates power is connected. If not, check that cord is plugged in completely. (See "Troubleshooting" on page 20 for more information.)

To maximize battery life and run time, use while connected to a power source whenever possible. The internal battery will automatically charge whenever the concentrator is connected to a power source. The LCD display will indicate whether the device is operating on battery or external AC power.

The fully charged battery will retain some level of charge for up to seven days in this device when not in use.

Note: Battery damage may result if the concentrator's battery is allowed to discharge completely.

PRECAUTION:

REMOVE BATTERY IF THIS DEVICE IS NOT GOING TO BE USED FOR MORE THAN SEVEN DAYS. STORE BATTERY IN A COOL, DRY PLACE.

PRECAUTION:

CHECK THAT THIS DEVICE OPERATES ON BATTERY AFTER DISCONNECTING FROM THE POWER SOURCE.

Note: When not using the battery inside the unit, be sure to store it in the protective sleeve that was provided with the original package.

Features and Controls

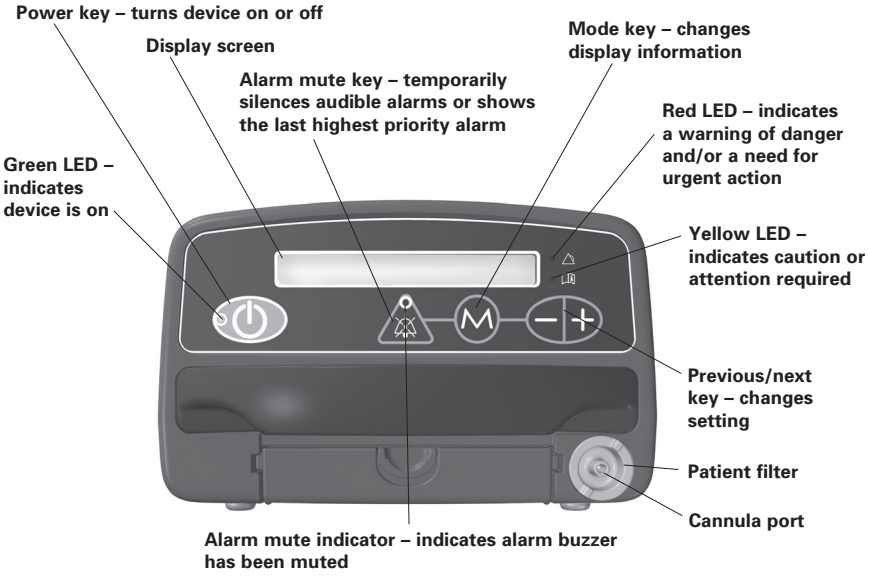


Figure 3.

Figure 4.

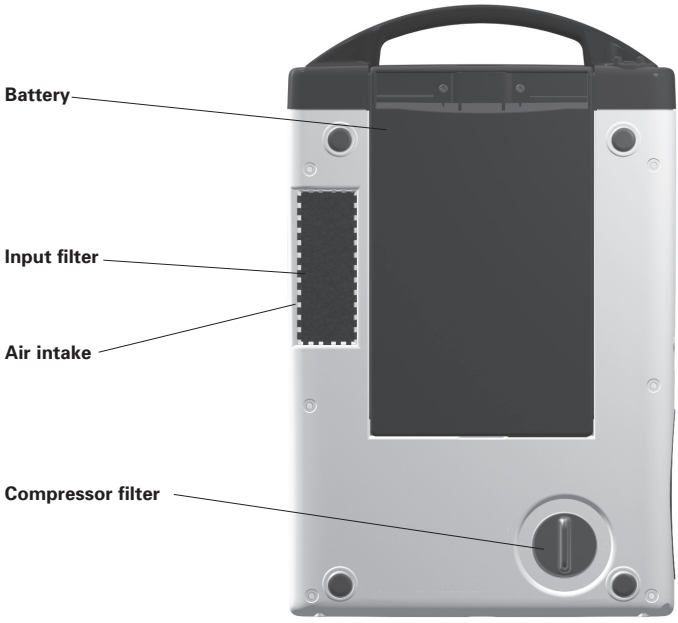


Figure 5.

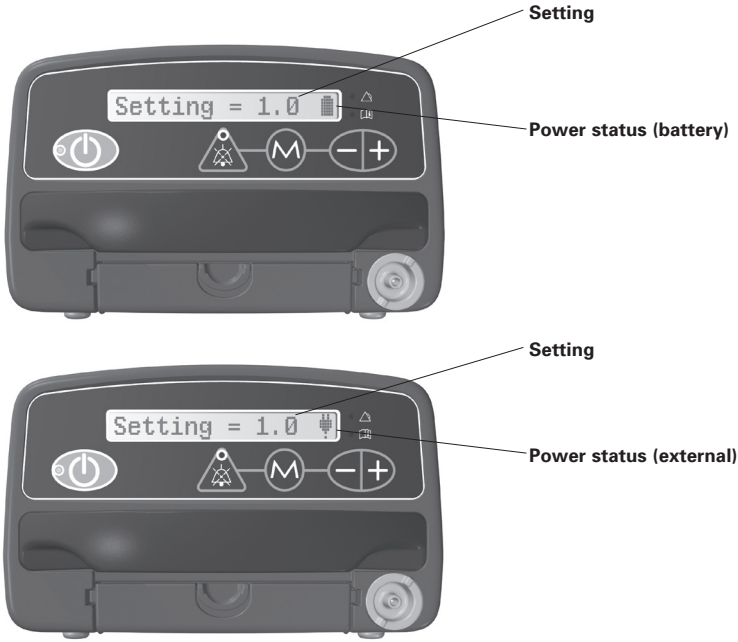


Figure 6.

ACCESSORIES

A variety of accessories can enhance the portability and use of the Portable Oxygen Concentrator. In addition to the device, the package contains accessories to get started and instructions for use. Refer to the Approved Accessories Guide for the complete list of available accessories.

Only use a nasal cannula with the following specifications:

- 7' (2.1 m) long
- High flow
- Three-fluted
- Crush-resistant
- Large internal diameter bore
- Straight non-tapered tips
- Suitable for up to 10 lpm

Note: Recommended model is Salter Labs 1600 HF cannula.

PRECAUTION:

ONLY USE APPROVED ACCESSORIES WITH THIS DEVICE. REFER TO THE APPROVED ACCESSORIES GUIDE FOR A COMPLETE LIST OF ACCESSORIES AND CANNULA APPROVED FOR USE WITH THIS DEVICE. USING UNAPPROVED ACCESSORIES OR CANNULA MAY IMPAIR THE PERFORMANCE OF THIS DEVICE.

Contact Customer Service for updated information and accessories or if additional, optional, or replacement accessories are needed.

Carrying Case

To reduce the risk of electric shock, always use the Portable Oxygen Concentrator with a carrying case (which also further reduces the device noise during operation). Insert the device in the case such that the display screen is visible through the clear plastic window and securely fasten all straps. When properly inserted, it should look like Figure 7. When using the carrying case, do not carry the concentrator by its handle; use the case's carrying strap.

WARNING:

RISK OF ELECTRIC SHOCK. DO NOT OPERATE THIS DEVICE WITHOUT THE CARRYING CASE.

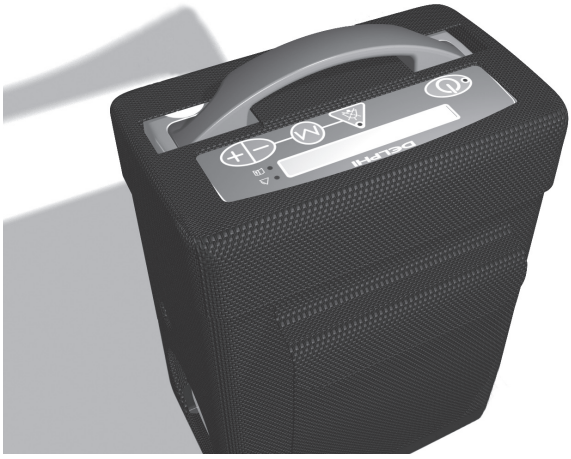


Figure 7.

Pull Cart

When using the Portable Oxygen Concentrator with a pull cart, attach and secure the concentrator with the straps as shown in Figure 8. The handle can be pulled out and adjusted for comfort.

Note: It is recommended that patients use the pull cart to transport the device whenever possible.

Figure 8.

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IMPORTANT:

Read “Warnings and Precautions” (page viii) before using this device.

The Portable Oxygen Concentrator is designed for ease of use, with all functions accessed through just a few keys on the control panel.

The Portable Oxygen Concentrator should be carried in its carrying case, placed on a cart, or used while laying on a table or upright on the floor. The patient should be within 7′ of this device during use.

Note: Except during startup and shutdown sequences, the backlight on the display screen will remain off. Pressing any key will turn the backlight “on” briefly. The backlight will also remain activated during an un-muted alarm condition.

CONNECTING NASAL CANNULA

PRECAUTION:

REPLACE THE CANNULA ON A REGULAR BASIS. CHECK WITH CUSTOMER SERVICE OR CLINICIAN TO DETERMINE HOW OFTEN THE CANNULA SHOULD BE REPLACED.

PRECAUTION:

ALWAYS FOLLOW CANNULA MANUFACTURER’S INSTRUCTIONS FOR PROPER USE.

Connect the tubing to the cannula port (oxygen discharge) as shown in Figure 9.

Figure 9.

To connect the cannula to the patient, position the cannula tips in patient's nostrils and pass tubing over both ears and under chin. Follow manufacturer's instructions.

Slide adapter up tubing to adjust for comfort and fit.

Once the cannula is secured, breathe normally through the nose. The Portable Oxygen Concentrator will detect a breath and deliver the oxygen during inhalation.

Note: Improper cannula placement may result in the Portable Oxygen Concentrator being unable to detect all respiratory efforts of the patient. Ensure cannula is connected securely and it has been fully inserted.

PRECAUTION:

PATIENTS WITH A FAST BREATHING RATE REQUIRING A HIGHER OXYGEN SETTING MAY REQUIRE MORE OXYGEN THAN THIS DEVICE CAN PRODUCE. THIS DEVICE MAY NOT BE APPROPRIATE IN THAT CASE. CONSULT CLINICIAN FOR ALTERNATIVE TREATMENT.

TURNING ON

To turn the Portable Oxygen Concentrator on, press the power key. The concentrator will chirp and the green, yellow, and red LEDs will flash once, while the screen displays concentrator software version information and total elapsed run time information. The green LED will then stay lit.

Note: No adjustments can be made until the startup sequence is completed.

ADJUSTING SETTING

Note: After powering on the Portable Oxygen Concentrator, the startup sequence will take approximately 35 seconds. Specified oxygen level will be reached within 10 minutes of use.

Increase or decrease the setting using the previous/next key. Pressing the next (+) key increases the setting 0.5, up to 5.0. Pressing the previous (-) key decreases setting 0.5, down to 1.0.

The current setting and power source (external power or battery; battery icon also shows approximate level of charge remaining) are shown on the display screen as shown in Figures 10 and 11.

Figure 10. Concentrator operating on battery power.

Figure 11. Concentrator running on external power.

RESPONDING TO ALARMS

PRECAUTION:

IF YOU ARE UNABLE TO HEAR OR SEE ALARMS, DO NOT HAVE NORMAL TACTILE SENSITIVITY, OR CANNOT COMMUNICATE DISCOMFORT, CONSULT CLINICIAN BEFORE USING THIS DEVICE.

Pressing the alarm mute key at any time will silence the buzzer. The length of the mute period depends on the severity of the alarm. (See "Alarm Indicators" on page 16.) During this mute period, the mute LED will remain illuminated, indicating the alarm buzzer is muted. Push the mute key again to unmute alarms. Pressing the mute key when there is no active alarm will mute any future medium or low priority alarms for eight hours. See "Troubleshooting" (page 20) for additional information on alarms.

TURNING OFF

PRECAUTION:

ALWAYS TURN OFF THIS DEVICE WHEN NOT IN USE.

To turn the Portable Oxygen Concentrator off, press and hold the power key. The device will chirp and the screen will display a shutdown message "Shutting off" for approximately five seconds, then go into low-power mode.

Note: Do not disconnect the AC power supply and remove the battery at the same time while the unit is running. Always use the power key to turn the device off. Wait until the device has completely shut down before disconnecting from power and removing the battery.

TRAVELING BY AIR WITH THE PORTABLE OXYGEN CONCENTRATOR

Contact Customer Service for information on airline regulations related to traveling with the Portable Oxygen Concentrator by air.

Maintenance and Cleaning

VERIFYING THE ALARM SYSTEM

At startup, the LEDs should light up and buzzer should sound to verify operation.

BATTERY CARE

Avoid letting battery deplete; operate device when connected to AC power whenever possible to help keep battery charged. Disconnect battery if the device will not be used for more than seven days, and store the battery in a cool, dry place.

Dispose of battery according to local regulations or contact Customer Service.

ENVIRONMENT/STORAGE

The Portable Oxygen Concentrator can operate in the following conditions:

- 41°F to 95°F (5°C to 35°C)
- 5% to 93% ± 2% relative humidity (non-condensing)
- Altitudes between 0' to 8,000' above sea level (0 km to 2.4 km)

When not in use, the Portable Oxygen Concentrator should be stored in a clean, dry environment between -4°F and 140°F (-20°C and 60°C).

Note: The Portable Oxygen Concentrator can be safely stored up to 15,000' (4,572 m) above sea level.

WARNING:

THIS DEVICE IS FOR CONTINUOUS OPERATION AT TEMPERATURES OF 95°F (35°C) DOWN TO 41°F (5°C), AND SHORT-TIME OPERATION FOR 25 MINUTES AT TEMPERATURES UP TO 104°F (40°C) AND 93% ± 2% RELATIVE HUMIDITY.

PRECAUTION:

NEVER LEAVE THIS DEVICE IN A HOT ENVIRONMENT. NEVER LEAVE THIS DEVICE IN A LOW-TEMPERATURE ENVIRONMENT. EXTREME HIGH OR LOW TEMPERATURES CAN DAMAGE THIS DEVICE.

PRECAUTION:

REMOVE BATTERY IF THIS DEVICE IS NOT GOING TO BE USED FOR MORE THAN SEVEN DAYS. STORE BATTERY IN A COOL, DRY PLACE.

ROUTINE MAINTENANCE

WARNING:

DO NOT USE LUBRICANTS ON THIS DEVICE OR ANY OF ITS ACCESSORIES.

PRECAUTION:

REPLACE THE CANNULA ON A REGULAR BASIS. CHECK WITH CUSTOMER SERVICE OR CLINICIAN TO DETERMINE HOW OFTEN THE CANNULA SHOULD BE REPLACED.

Device will indicate with an alarm when a filter or device needs to be cleaned or changed. (Also, see "Troubleshooting" on page 20.)

Cleaning and Changing Filters

Filters in the Portable Oxygen Concentrator should be periodically washed or replaced as indicated by messages on the display screen.

INPUT FILTER

The input filter is designed to keep particles out of the device and should be washed frequently, especially if used in a contaminated environment (such as near construction sites, etc.).

Note: If a replacement input filter is required, contact Customer Service.

PRECAUTION:

DO NOT OPERATE THIS DEVICE WITHOUT THE INPUT FILTER IN PLACE. IF FILTER IS REMOVED, PARTICLES MAY BE DRAWN INTO THE SYSTEM AND MAY DAMAGE THIS DEVICE.

PRECAUTION:

ALWAYS DISCONNECT POWER AND TURN OFF THIS DEVICE BEFORE CLEANING.

Wash the input filter by following these steps:

1. Remove the filter from the device.
2. Rinse under tap water without soap.
3. Air dry.

PATIENT FILTER

The patient filter is designed to trap airborne particulates. If the device indicates the patient filter should be replaced, contact Customer Service for replacement filter. Replace as shown in Figure 12.

Figure 12.

COMPRESSOR FILTER

The compressor filter is designed to trap airborne particulates. If the device indicates the compressor filter should be replaced, contact Customer Service for replacement filter. Replace as shown in Figure 13.

Figure 13.

EXTERIOR CLEANING

WARNING:

DO NOT SUBMERGE THIS DEVICE IN LIQUID. DO NOT EXPOSE TO WATER OR PRECIPITATION. DO NOT EXPOSE TO DUSTY CONDITIONS.

PRECAUTION:

DO NOT USE CLEANING AGENTS OTHER THAN THOSE SPECIFIED IN THIS MANUAL. ALLOW THE CLEANING SOLUTION TO DRY FROM THE CLEANED SURFACE BEFORE USE.

Clean the exterior with a soft cloth slightly dampened with soapy water or a mixture of 10% household bleach in water.

ACCESSORY CLEANING

Refer to the original cannula manufacturer's instructions for cleaning the nasal cannula.

DEVICE REPAIR

Do not attempt to repair the device. Contact Customer Service for assistance (see "Troubleshooting" on page 20).

DEVICE DISPOSAL

Contact Customer Service regarding disposal of the device.

Alarm Indicators

If the Portable Oxygen Concentrator detects an alarm condition, it will indicate the alarm visually and audibly within 10 seconds. There are four levels of alarms: critical high priority, high priority, medium priority, and low priority. Each is indicated differently by the backlit display; green, yellow, and red LEDs; and buzzer, as indicated below. In each case, the alarm message and power status will override the current display.

Note: All alarm conditions and parameters are factory preset; conditions and parameters cannot be changed or adjusted by the user.

Alarm Status	Audible Tone	Visual Indicator	Mute Time
Critical high priority	Ten beeps per burst, burst repeats every 3 seconds	Solid red LED (and device shuts off automatically)	20 minutes
High priority	Ten beeps per burst, burst repeats every 3 seconds	Flashing red LED	20 minutes
Medium priority	Three beeps per burst, burst repeats every 8 seconds	Flashing yellow LED	8 hours
Low priority	Three beeps per burst, burst repeats every 10 minutes	Solid yellow LED	24 hours

Note: If two alarm conditions exist at the same time, the highest priority alarm is indicated. If two or more alarm conditions of equal priority exist at the same time, the most recent one will be displayed.

Note: The most recent alarms indicated by the device are logged for reference by service personnel. This log is maintained even if the device is powered down or if power is lost for any other reason.

Note: If the mute key is pressed prior to an alarm condition (for example, to mute the device in a movie theater), critical high priority and high priority alarms will override the mute function; medium and low priority alarms will be muted for eight hours from the time the key was pressed. Press the mute key off to display the last highest priority alarm. Press the mute key on again to reset the eight-hour timer.

ALARMS

When the Portable Oxygen Concentrator sounds an alarm, a corresponding message will be displayed on the screen. Take appropriate action as directed in the charts below.

Critical High Priority Alarms

Note: These alarms will disable the Portable Oxygen Concentrator immediately.

Alarm Message	Description	Action
Charge Battery	Battery needs charging.	Recharge the battery pack by plugging in to power supply. Ensure all connections are made securely.
XX: Service!*	Service required.	Contact Customer Service.

*Value: 01-20

High Priority Alarms

Note: These alarms will allow the Portable Oxygen Concentrator to continue operating.

Alarm Message	Description	Action
Check Vents	Device is unable to maintain oxygen purity.	Be sure air inlet/outlet has not been blocked. If alarm persists, contact Customer Service.
Low Battery	Estimated battery life less than 17 minutes.	Charge the battery pack by plugging in to power supply. *Note: The message will be automatically cleared when plugged in to power supply.*
XX: Service!*	Service required.	Contact Customer Service.

*Value: 21-50

Medium Priority Alarms

Alarm Message	Description	Action
Check Cannula	No breath detected for 5 minutes.	Check the cannula connection. Be sure to breathe through nose. If alarm persists, contact Customer Service. *Note: The message will be automatically cleared when breathing is detected.*
XX: Service*	Service required.	Contact Customer Service.

*Value: 51-70

Low Priority Alarms

Alarm Message	Description	Action
Replace C-filtr	Compressor filter needs replacement.	Replace filter. Press and hold mute key for more than 4 seconds to reset the hour counter.
Replace P-filtr	Patient filter needs replacement.	Replace filter. Press and hold mute key for more than 4 seconds to reset the hour counter.
Wash I-filtr	Input filter needs to be cleaned.	Wash input filter. Press and hold mute key for more than 4 seconds to reset the hour counter.
Replace batt	Main battery has exceeded 300 recharge cycles.	Contact Customer Service for replacement. *Note: This alarm will be automatically cleared once a new battery is inserted. Battery will continue to function after 300 recharge cycles, but for a shorter time than a new battery.*
XX: Service*	Service required.	Contact Customer Service.

*Value: 71-99

Other Messages

Message	Description	Action
Power removed	External power has been disconnected; unit is now running on battery.	No action is required.
SW Ver N.NNN	Display of software version during startup and calibration. This includes test of beeper and LEDs.	No action is required.
Self test	Indicates unit is going through its test at startup. Displayed for approximately 10 seconds.	No action is required.
Shutting off	Displayed while unit goes through its power-down sequence.	No action is required.
External power	External power is connected.	No action is required.

Other Messages, continued

Message	Description	Action
Battery low	Estimated battery life less than 17 minutes. The unit will also generate a high priority alarm as described above.	Charge the battery pack by plugging in to power supply. *Note: The message will be automatically cleared when plugged in to power supply.*
Fully charged	Displayed as the battery menu item when the battery is 100% charged.	No action is required.
Checking power	Displayed as the battery menu item when the battery status has recently changed and the unit software is analyzing the change in status.	No action is required.
No battery	Displayed as the battery menu item when there are no communications with the battery.	Verify that the battery pack is correctly installed. Contact Customer Service if the battery is fully inserted and the message continues to be displayed longer than 30 seconds.
BattLife NN%	Displayed percentage of battery charge if at least 10% and there is no external power connected.	Message is displayed when mode key is pressed.
Charging: NN%	NN% displays the current battery charge level. Displayed when battery charge is greater than 10% but less than 100% and there is external power connected.	Message is displayed when mode key is pressed.
Charging	Battery charge is less than 10% and there is external power connected.	Message is displayed when mode key is pressed.
RT XXXXX	Non-resettable total elapsed time indicator (hours).	No action required.
Breath rate XX	The patient's average breath rate when the device is delivering the maximum amount of oxygen and the bolus is reduced. If no breaths are detected, the most recent breath rate is shown.	Reduce activity level. Be sure air inlet/outlet has not been blocked. *Note: The message will automatically clear when the device returns to normal operation.*
Alarm cleared	A previously set alarm has been automatically cleared.	No action required.

Troubleshooting

Problem	Possible Cause	Troubleshooting
System becomes inoperative	• System may be disconnected from the power source. • System may be turned off. • Critical high priority alarm has occurred.	• Check that the system is connected securely to the power source. • Ensure the system is powered on. • Examine the system for damage or exposure to liquids. • If problem persists, contact Customer Service.
Any alarm sound or either  (red) or  (yellow) LED lit	• See "Alarm Indicators" on page 16.	• See "Alarms" on page 16.
Battery not charging	• Power is not connected.	• Check connections to ensure: 1. Round receptacles are secure in unit. 2. Power cord is connected to AC/DC supply or automotive DC adapter is connected, if applicable. 3. Power cord is connected to wall outlet, if applicable. 4. Wall outlet has power.
	• Battery is not fully inserted. • Battery is inoperable.	• Ensure battery is fully seated and latch is secure. • If problem persists, contact Customer Service.

Appendix 1: Technical Description

Size: 7.4" W x 4.6" D x 11.6" H (188 mm W x 117 mm D x 295 mm H)

Unit weight: Less than 10 lbs (without carrying case or cart)

Power requirements: 100-240V AC (± 10%), 50-60 Hz; battery power 18V DC, 6.7 amps; DC adaptor, 18V DC, 6.7 amps *(Note: See Approved Accessories Guide for model and part number of AC power supply.)*

Purity: 90% ± 3% (22°C ± 3°C, 14.29 psia ± 0.04 or 739 mmHg at 40% ± 15% relative humidity) at all flow rates

Setting: User adjustable 1.0 to 5.0 (with 0.5 increments) (min. 1.0; max. 5.0)

Setting indicator: LCD display

Maximum oxygen discharge pressure: 17 psi at setting of 5.0

Humidity range: 5% to 93% ± 2% non-condensing

Operating altitude: 0' to 8,000' relative to sea level (0 km to 2.4 km)

Sound pressure level (measured 1 m from edge of chassis): Less than 50 dB(A) average

Type of protection (electrical): Class I

Degree of protection (electrical): Type BF

Degree of protection (water): IPX2

Degree of safety (flammable anesthetic mixture): Not suitable for use in the presence of a flammable anesthetic mixture

Operation: Continuous operation at temperatures of 95°F (35°C) down to 41°F (5°C), and short-time operation for 25 minutes at temperatures up to 104°F (40°C).

Alarm sound pressure range: 65 to 85 dB(A)

Alarm system delays: Less than 10 seconds after detection (low oxygen alarms if oxygen is less than 82% volume fraction at specified environmental conditions)

Oxygen concentrator status indicator: High priority alarm that indicates when oxygen concentration drops below 82%

Maximum Temperature: Under extreme environmental and operating conditions, specific maximum surface temperatures are listed below. Each of these specific surfaces also lists an expected user contact limit as follows:

The Key panel can reach up to 140°F (60°C). This surface is intended to be touched for less than one minute at a time. The clear plastic window on the carrying case can reach up to 118.4°F (48°C). This surface is intended to be touched for less than ten minutes at a time. The remainder of the carrying case can reach up to 109.4°F (43°C). This surface has no time limitation on user contact.

Appendix 2: Technical Information

ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Portable and mobile radio frequency (RF) communications equipment can affect devices such as the Portable Oxygen Concentrator. As such, the device should not be used adjacent to other equipment. If this is not practical, then observe the device to make sure it is operating properly at all times.

Guidance and manufacturer's declaration: electromagnetic emissions

The Portable Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the concentrator should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment/guidance
RF emissions CISPR 11	Group 1	The Portable Oxygen Concentrator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The concentrator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration: electromagnetic immunity

The Portable Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the concentrator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 15kV contact ± 8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Portable Oxygen Concentrator required continued operation during power main interruptions, it is recommended that the concentrator be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Portable Oxygen Concentrator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	20 V/m 80 Mhz to 2.5 Ghz	20 V/m	

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Portable Oxygen Concentrator is used exceeds the applicable RF compliance level above, the concentrator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the concentrator.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Portable Oxygen Concentrator

The Portable Oxygen Concentrator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The monitor user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance (m) according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

Trademarks

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Airline Travel Guidelines

When traveling by air, it is recommended the guidelines listed below be followed:

1. The patient must be capable of seeing the alarm indicator lights, hearing the various warning alarms, and taking the appropriate actions should the unit fail to detect the user's breathing or a general malfunction occurs. If the patient is not capable of the above requirement, they must be traveling with someone who is capable of performing those functions for the user.
2. Person using the Portable Oxygen Concentrator (POC) must not be seated in an aisle, normal exit row, or emergency exit so as not to restrict access to the aisle by other passengers. Patients should stow POC while in use, underneath seat, so that it does not interfere with the movement of other passengers. If patients are not required to use oxygen during takeoff, landing, or movement on the surface, they must stow the POC according to airline regulations (underneath seat or in overhead cabin).
3. Patient is responsible to carry sufficient amount of batteries to last for the entire trip, including layovers and/or possible flight delays.
4. Batteries, not being used or extra, must be stowed in their protective cover or/and placed inside the carrying case or placed inside an approved carry-on baggage, packaged to prevent short circuits and protected from physical damage.
5. Patient must obtain a signed, licensed clinician statement that medical oxygen is necessary for the duration of the flight and the maximum setting allowed onboard an aircraft.
6. The patient must inform the aircraft operator and its crew that the POC may be used onboard the aircraft.
7. In the event of an alarm, the POC must be turned off or alarms muted.
8. Only oxygen approved lotions or salves may be used by the patient.
9. The patient must operate the POC with battery power only (do not use the car charger) while onboard the aircraft. The A/C power cord and car charger options are not approved for onboard aircraft use.

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